Notes of Terrazole Mitigation Discussion

11:00 a.m., May 23, 2000
U.S. EPA Office of Pesticide Programs
Room 650 Crystal Mall 2
1921 Jefferson Davis Highway
Arlington VA 22202

Attendees: Representatives from Uniroyal Chemical Company (technical registrant), USDA, U.S. EPA (Sign-in sheet attached)

The meeting was called by U.S. EPA staff from the Special Review and Reregistration Division (SRRD) to begin discussion on potential mitigation measures for Terrazole. The Agency provided the preliminary human health and environmental risk assessments to Uniroyal, the technical registrant, and USDA for their review. The risk assessments were then revised, in part to reflect the registrant's comments and in part to incorporate new information that was not available when the preliminary assessments were prepared.

SRRD staff summarized the risks of concern, as described in the attached document, "Terrazole Risk Issues/Mitigation, May 23, 2000." The greatest risk concerns identified in the risk assessments, though not the only ones, are associated with golf course turf use. These include:

- surface water expected environmental concentrations (EECs) that exceed the level of concern for cancer risk from drinking water for the general population;
- occupational risk for handlers for all use sites;
- acute and chronic risks for birds, mammals and aquatic organisms, particularly aquatic plants

Representatives of Uniroyal ("the registrant") expressed concern that the surface water EECs were derived from a Tier 1 GENEEC model and consequently are overestimated. They suggested conducting a Tier 2 assessment using PRZM/EXAMS. PRZM/EXAMS does not have a scenario for assessing golf course use. The registrant indicated that they have a consultant who has developed a methodology for using PRZM/EXAMS to assess golf course use, and committed to submit further information to EPA on this methodology.

The registrant questioned a number of assumptions in the occupational risk assessment, including the number of applications for golf course and cotton uses, the dermal absorption factor used, and the amount of potting soil that could be handled in one day. They disagreed with the Agency's concern about underestimating inhalation exposure in its assessment. The Agency's concerns arose from a greenhouse potting soil study provided by Uniroyal that indicated that 70% of exposure shown in the study was from the inhalation route. The Agency agreed to look again at the study to verify its interpretation.

Uniroyal expressed concern about the number of applications per season assumed for the cancer risk estimates. Agency staff invited the registrant to provide more accurate data. Uniroyal

indicated that they would conduct a survey of a representative sample of users to obtain this information.

Uniroyal indicated that they have a chemical-specific study that indicates a 7% dermal absorption factor. They said the study was not submitted to the Agency because it was not designed according to EPA guidelines. They said they would submit the study for review immediately with the hope that we might agree on a dermal absorption factor somewhere between 7% and our default of 100%.

Many of the handler scenarios with risks of concern involve the granular formulation, produced by Scotts. Particular problems are associated with application of granules with a push-type spreader. Uniroyal was not prepared to offer mitigation suggestions for those products but said they would contact Scotts for use pattern information that would enable them to prepare a mitigation proposal.

The Agency indicated that the Reregistration Eligibility Decision is being developed now and is expected to be completed in June, 2000. The Agency is willing to consider a proposal for exposure reduction associated with golf course use but staff anticipates that it would be several months before it would be received and reviewed. The Agency asked that the registrant propose mitigation measures to address these risks in the interim.

AGENDA

Mitigation Meeting
May 23, 2000
11 a.m.
Room 650 Crystal Mall 2

Attendees: U.S. EPA, Uniroyal Chemical Company, USDA.

1. Introduction

2. Summary of Risks

3. Use Information to Help Characterize Risks

4. Data Gaps

Terrazole Risk Issues/Mitigation

May 23, 2000

Risk Summary

Dietary exposure (food): not a concern

Dietary exposure (drinking water): may be a concern

Golfers: not a concern

Workers: The current product labels vary widely in the amount of PPE they require. We assess handler scenarios using four different levels of protection: baseline PPE; baseline + gloves; coveralls, gloves and OVR respirator; and engineering controls (water soluble bag or closed system). If risks at baseline PPE are of concern, they are evaluated with the next highest level of protection, and so on until an MOE of at least 100 or a cancer risk estimate of 10^{-6} is reached. Some of the scenarios assessed required PPE above and beyond current labels to get MOEs to 100. Some scenarios are of concern with maximum PPE; some are of concern even with water soluble bags.

We recognize that some of the application methods assessed are not commonly used or not used at all such as the belly grinder and dust blower. If a feasible method is allowed on the label, we need to assess it. Some of these methods are of great concern. We understand the belly grinder and dust blower are no longer used, and we anticipate tightening up the label language to reflect this.

We also realize that our figures on total usage differ somewhat from those provided by the registrant; however, in general this will not change the occupational risk assessment. Worker risks are based on daily exposures.

Ecological: acute and chronic risks for birds, mammals, fish, aquatic plants associated with turf use

Drinking Water

Results of a Tier 1 assessment using GENEEC indicate that chronic drinking water risk may be a concern. Based on the notes of the conference call, we re-ran the model and assumed 5 applications on tees and greens, and 2 applications on fairways. The results:

tees/greens (5 apps) + fairways (2 apps):	32.3 ppb
tees/greens only (5 apps):	7.8 ppb
tees/greens only (2 apps):	4 ppb

Based on use on tees and greens only, there is no concern for infants and children; however we are still concerned about cancer risk for the general population (DWLOC = 1 ppb).

Current labels all include tees, greens and fairways.

Worker Risks

Some of the current labels are more protective than others. The level of PPE required to achieve an MOE of 100 or cancer risk of 10-6 is greater than what is currently required on some products. Scenarios that are of concern even with the highest level of PPE are those we would like to discuss today.

One of the underlying assumptions in the cancer risk estimates is the distinction between private and commercial applicators. We realize that most golf courses do not contract with commercial applicators; however, some do and we need to take that into consideration. The difference between private and commercial applicators for purposes of this assessment is the number of applications made per season.

Cotton

1. Mixing/loading dry flowable for in-furrow application
   With coveralls, chemical-resistant gloves and OVR respirator (CGR):
   commercial cancer risk: $1x10^{-5}$ (typical application rate)

   Assumes 12 applications per year

   Current label: requires baseline+waterproof gloves+OVR respirator

Seed Treatment

Although seed treatment products are not being marketed, the registrant could choose to market them at any time. The risk assessment must identify risks based on what exposures could occur under current labeling.

Scenarios 1 and 2 below are based on Uniroyal's Vitavax study; we have no chemical-specific data that would enable us to refine these risk estimates. Additional information regarding number of applications per year would help refine our cancer risk estimates.

1. Loading/applying liquid for commercial seed treatment

   With baseline PPE plus chemical-resistant gloves:
   private cancer risk: 4.3×10^{-5} (typical app rate)
   commercial cancer risk: 1.3×10^{-4} (typical app rate)
   IT MOE: 42 (high app rate)

   Assumes: 20 private apps per year, 60 commercial apps per year
   Represents dermal exposure only; underestimates inhalation exposure (assumes 1%)

   Current labels meet or almost meet this level of PPE

2. Loading dust for commercial seed treatment

   Water-soluble bag (WSB) was needed to get some MOEs to 100

   With WSB:
   private cancer risk: 5.4×10^{-6} (typical app rate)
   commercial cancer risk: 1.6×10^{-5} (typical app rate)

   With coveralls, chemical-resistant gloves, & OVR-respirator (CGR):
   private cancer risk: 7.3×10^{-5} (typical app rate)
   commercial cancer risk: 2.2×10^{-4} (typical app rate)
   IT MOE: 60 (typical app rate)

   Assumes: 20 private apps per year, 60 apps per year
   Underestimates inhalation exposure (assumes 1%)
   Based on Uniroyal's Vitavax study

   Some current labels require this level of PPE already; one does not

3. Mixing/loading/applying dry in planter box

commercial cancer risk: 1.0×10^{-4} (typical app rate)
IT MOE: 45 (typical app rate)

Assumes: 21 commercial apps per year
Baseline plus chemical-resistant gloves

Some current labels require this level of PPE already; one does not

Golf Course Turf

1. Mixer/loader, wettable powder for groundboom

WSB required to get MOEs to 100
With WSB: cancer risk 5.0×10^{-6} (private) and 1.5×10^{-5} (commercial)

With CGR: ST MOE = 87, 43, 22 (low, typ, high app rate)
IT MOE = 32, 16, 8 (low, typ, high app rate)
cancer risk 6.8×10^{-5} (private) and 2.0×10^{-4} (commercial)

Assumes: 3 private apps/year, 30 commercial apps/year, typical app rate
40 acres

Current labels: Some require CGR, some do not

2. Mixer/loader/applicator, wettable powder for groundboom

WSB required to get MOEs to 100
With WSB: cancer risk 7.8×10^{-6} (private) and 1.6×10^{-5} (commercial)
IT MOE 71

With CGR: ST MOE = 64, 40, 20 (low, typ, high app rates)
IT MOE = 24, 15, 7 (low, typ, high app rates)
Cancer risk 7.3×10^{-5} (private) and 1.5×10^{-4} (commercial)

Assumes: For cancer risk, 5 private apps/year, 15 commercial apps/year,
typical application rate, 40 acres
For IT MOE, high app rate and 40 acres

Current labels: Some require CGR, some do not

3. All scenarios involving belly grinder and push-type spreader:

Loading/applying granules using belly grinder
Loading/applying granules using push-type spreader

MOEs 13-35 with coveralls, gloves, respirator
Cancer risks 10^{-4}, 10^{-5}

Ornamentals

1. Mixing/loading/applying granules to potting soil

With CGR:
ST MOE: 72
IT MOE: 27

Assumes: 10 c.y.
3 apps/year for private
9 apps/year for commercial

Current labels all require baseline+waterproof gloves

2. Loading/applying granules (5G) with tractor-drawn spreader

With CGR:
IT MOE: 59
private cancer risk 1.1×10^{-5}
commercial cancer risk 3.4×10^{-5}

Assumes: 5 acres
3 apps/year for private
9 apps/year for commercial

Current labels all require baseline+waterproof gloves

3. Dispersing granules by hand

With CGR:
ST MOE: 13
IT MOE: 4.9
private cancer risk: 2.5×10^{-5}
commercial cancer risk: 7.5×10^{-5}

Assumes: 5000 s.f.

3 apps/year for private
9 apps/year for commercial

Current labels all require baseline+waterproof gloves

4. All scenarios involving belly grinder and push-type spreader:
   Loading/applying granules (8G) with belly grinder
   Loading/applying granules (5G) with belly grinder
   loading/applying granules (5G) with push-type spreader
   Loading/applying granules (8G) with push-type spreader
   Loading/applying granules (5G) with tractor-drawn spreader

   MOEs 13-35 with CGR
   cancer risks 10^{-4} and 10^{-5} with CGR

Ecological Risks

Mammals, birds, aquatic organisms:

acute and chronic risks associated with turf use, typical and high app rates
risks associated with parent compound and degradates
granular and nongranular formulations

Data Requirements

The following studies reflect our current thinking on the data that would be needed to fully characterize the risk. Some of the studies have been requested previously. Others may be required in the RED.

Field trials to support registration on tomatoes
Multi-generation reproduction study in rats (protocol to include early thyroid measurements)
Chronic dog feeding study
Mouse carcinogenicity
Storage stability of 3-Carb-T in animal commodities
Product chemistry data for dry formulations (vapor pressure)
Dermal exposure for indoor applicators
Inhalation exposure for indoor applicators
Freshwater invertebrate acute toxicity of 3-DCMT and 3-Carb-T
Estuarine/marine invertebrate acute toxicity of 3-DCMT
Estuarine/marine fish acute toxicity of 3-DCMT
Freshwater fish acute toxicity of 3-Carb-T